FINAL –

Number/Name: P-17-0119 / [redacted]

SUMMARY INFORMATION

EPA estimated the human health hazard of this chemical substance based on its estimated physical/chemical properties, available PMN data, and by comparing it to structurally analogous chemical substances for which there is information on human health hazard.

Based on the hazard determination and available qualitative risk information, EPA did not identify risks for the PMN substance.

Human Health Hazard:

- Absorption of the parent polymer is expected to be NIL all routes based on the high molecular weight. Poor absorption by all routes is expected for a silane hydrolysis product based on physical chemical properties.
- Irritation to the eyes, skin, lung, and mucous membranes is considered possible but unlikely due to size of compound and water solubility.
- Lung effects for respirable particulates containing the PMN substance, based on insoluble large molecular weight polymer species persisting in the lungs and leading to lung overload.

Human Health Risk:

- Inhalation exposure to workers was not assessed because [redacted] has jurisdiction over the use that results in worker inhalation exposure.
- Irritation hazards for workers via dermal exposure were identified but cannot be quantified due to lack of dose-response information for this hazard. However, exposures can be controlled by the appropriate use of personal protective equipments (PPE), such as gloves. EPA expects that workers will use appropriate PPE consistent with the Safety Data Sheet prepared by the submitter, in a manner adequate to protect them.
- Risks to the general population were not evaluated because expected releases are expected to be negligible (below modeling thresholds).
- Risks to consumers were not evaluated because consumer uses were not identified as conditions of use.

Potentially useful information would inform understanding of:

- Pulmonary effects

FINAL –

PART A

SAT Date: 07/07/2017

Health Assessor: Amy Babcock

Structure:

PMN: P-17-0119	Submitter: [redacted]		Manu.	Import
Max. PV (KG):	[redacted]	Binding Option Marked:		X
MW: [redacted]	[redacted]	% < 500 [redacted]	% <1000	CASNO [redacted]

PMN Structure	Prop.	Meas.	Est.
[redacted]	MP	[redacted]	
	BP		
	Pres.		
	VP		
	S-H2O		
	log P		

[redacted]	Analogs: No suitable analogs found.
USE: [redacted]	other_uses No other uses found.

- **CASRN:** [redacted]
- **Chemical Category:** Not applicable
- **Chemical Category Health Concerns:**
- **Category Testing Strategy:**
- **PMN Health Rating**
  - 1-2
  - PMN P1, B1, T2
  - Hydrolysis Product P3, B1, T2
- **SAT Key Words:** LUNG; UNCERT IRR-E, S, L, MM
- **Absorption:** Absorption of the parent polymer is expected to be NIL all routes based on the high molecular weight. Poor absorption by all routes is expected for a silane hydrolysis product based on physical chemical properties.
- **SAT Health Summary:** Irritation to the eyes, skin, lung, and mucous membranes is consisidered

possible but unlikely due to size of compound and water solubility. Concern for lung toxicity if inhaled; insoluble large molecular weight polymers may persist in the lungs and lead to lung overload, sustained inflammatory response and secondary effects.

- **PMN Data:** (study summary, POD)
  - Test data submitted with PMN:
    (-) Ames assay with and without activation;
    (-) Sensitization;
    acute oral LD50 > 2000 mg/kg
- **Analog Data:** (analog, structure, study summary, POD)
  - No data available

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(38) ANALOGS:			
PMN or CAS No.	Chem. Name	Structure	TSCA Y/N
	No suitable analogs found.		

- **Other Information:** (structural alert or component of interest, basis, etc.)
  - SDS
    - **SDS includes [redacted] and [redacted] as components. Information from the SDS regarding those components is specifically excluded from this assessment.**

SECTION 2 : Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Flammable liquids, Category 3	H226 : Flammable liquid and vapour.
Skin irritation, Category 2	H315 : Causes skin irritation.
Eye irritation, Category 2	H319 : Causes serious eye irritation.
Specific target organ toxicity – single exposure, Category 3	H335 : May cause respiratory irritation.
Specific target organ toxicity - repeated exposure, Category 2	H373 : May cause damage to organs through prolonged or repeated exposure.
Chronic aquatic toxicity, Category 3	H412 : Harmful to aquatic life with long lasting effects.

Classification (67/548/EEC, 1999/45/EC)

Flammable R10 : Flammable.

Harmful R20/21 : Harmful by inhalation and in contact with skin.

R48/20/21/22 : Harmful : danger of serious damage to health by prolonged through inhalation, in contact with skin and if swallowed.

Irritant R36/37/38 : Irritating to eyes, respiratory system and skin.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :

Signal word : Warning

Hazard statements :
- H226 Flammable liquid and vapour.
- H315 Causes skin irritation.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.
- H373 May cause damage to organs through prolonged or repeated exposure.
- H412 Harmful to aquatic life with long lasting effects.

Precautionary statements : **Prevention :**
- P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
- P273 Avoid release to the environment.
- P280 Wear protective gloves/ protective clothing/ eyeprotection/ face protection.

Response :
- P304 + P340 + P312 IF INHALED : Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or doctor/ physician if you feel unwell.
- P314 Get medical advice/ attention if you feel unwell.
- P337 + P313 If eye irritation persists : Get medical advice/attention.

Hazardous components which must be listed on the label : [redacted]

2.3 Other hazards

Vapours may form explosive mixture with air.

8.2 Exposure controls

Engineering measures

Minimize workplace exposure concentrations.

Use only in an area equipped with explosion proof exhaust ventilation. Use with local exhaust ventilation.

Personal protective equipment

Eye protection : Wear the following personal protective equipment :
Safety goggles

Hand protection

Material : Impervious gloves
Flame retardant gloves

Remarks : Choose gloves to protect hands against chemicals depending on the concentration and quantity of the hazardous substance and specific to place of work.
Breakthrough time is not determined for the product.
Change gloves often! For special applications, we recommend clarifying the resistance to chemicals of the aforementioned protective gloves with the glove manufacturer. Wash hands before breaks and at the end of workday.

Skin and body protection : Select appropriate protective clothing based on chemical resistance data and an assessment of the local exposure potential.
Wear the following personal protective equipment :
Flame retardant antistatic protective clothing.
Skin contact must be avoided by using impervious protective clothing (gloves, aprons, boots, etc).

Respiratory protection : Use respiratory protection unless adequate local exhaust ventilation is provided or exposure assessment demonstrates that exposures are within recommended exposure guidelines.

Filter type : Organic vapour type (A)

SECTION 11 : Toxicological information

11.1 Information on toxicological effects

Information on likely routes of exposure : Inhalation
Skin contact
Ingestion
Eye contact

Acute toxicity

Not classified based on available information.

Product :

Acute inhalation toxicity : Acute toxicity estimate : > 20 mg/l
Exposure time : 4 h
Test atmosphere : vapour
Method : Calculation method

Acute dermal toxicity : Acute toxicity estimate : > 2,000 mg/kg
Method : Calculation method

Skin corrosion/irritation

Causes skin irritation.

Serious eye damage/eye irritation
Causes serious eye irritation.

Respiratory or skin sensitisation
Skin sensitisation : Not classified based on available information.
Respiratory sensitisation : Not classified based on available information.

Germ cell mutagenicity
Not classified based on available information.

Carcinogenicity
Not classified based on available information.

Reproductive toxicity
Not classified based on available information.

STOT - single exposure
May cause respiratory irritation.

STOT - repeated exposure
May cause damage to organs through prolonged or repeated exposure.

Aspiration toxicity
Not classified based on available information.

Point of Departure Selected and Basis:

POD FOR LUNG OVERLOAD – INSOLUBLE POLYMER

POD type (NOAEL/LOAEL): LOAEC
POD Chemical: polyvinyl chloride (PVC) powder
POD Route: Inhalation
POD Endpoint: Decreased alveolar clearance
POD Value: The lowest reported point of departure was a LOAEC of 3.3 mg/m3
POD Basis: Rat, strain NS, female; 7 months duration at 25 hours/week; recovery period 100 days; air exposed control group; 0, 3.3, 8.3 or 20.2 mg/m3 doses
POD Benchmark MOE: 1,000 (10 for LOAEC to NOAEC * 10 interspecies UF * 10 intraspecies UF)
Reference: Muhle et al., 1990. J Aerosol Sci. 21(3):374-377
POD for Lung Overload – Insoluble Polymer

Exposure Routes of Interest:

- _X Inhalation
- _X Dermal
- _X Ingestion

PART B

Focus Date: 7/27/17

Focus Assessor: ~~Baier-Anderson~~ UPDATED 8/27/18 by Amy Babcock

USES and EXPOSURES:

- **Uses:** Binder resin [redacted]
- **Worker Exposure:**
  - **Inhalation:** Mist [redacted]

    This value is the "what-if" Potential Dose Rate based on OPPT's Spray Coating inhalation model. EPA has determined that [redacted] has jurisdiction over the use that results in this exposure, thus RAD will not evaluate the risks associated with this exposure.

  - **Dermal:** [redacted] mg/day

- **General Population Exposure:** Exposure expected to be neglible (below modeling threshold).

- **Consumer Exposure:** Not expected as there are no identified consumer uses.

RISK CALCULATIONS:

- **Worker Calculations:**
  - Risks to workers for irritation via dermal exposure cannot be quantified due to lack of dose-response information for this hazard. However, exposures can be controlled by the appropriate use of personal protective equipments (PPE), such as gloves. EPA expects that workers will use appropriate PPE consistent with the Safety Data Sheet prepared by the submitter, in a manner adequate to protect them.

- **General Population Calculations:**
  - Not evaluated as there are no expected general population exposures.

- **Consumer Calculations:**
  - Risk to consumers was not evaluated because consumer use was not identified as a condition of use.